SH

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OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year: 2009

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

REGISTRATION NUMBER: 51-R-0079

Customer Number: 21555

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include ZIP Code)*

Bridge Global Pharmaceutical Services Inc
610 Professional Drive
Gaithersburg, MD 20879

Telephone: (240) 364 6400

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)*

FACILITY LOCATIONS *(Sites)* *See Attached Listing*

(b)(2)High, (b)(7)f

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use APHIS Form 7023A)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	0	97	22	1	120
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	131	0	131
7. Hamsters	0	0	0	0	0
8. Rabbits	0	1098	82	13	1193
9. Non-human Primates	0	165	120	2	287
10. Sheep	0	0	0	0	0
11. Pigs	0	6	11	0	17
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

(b)(6), (b)(7)c

DATE SIGNED 11-23-09

APHIS FORM 7023
AUG 2009

NOV 24 2009

ANNUAL REPORT OF RESEARCH FACILITY

Certificate Number: 51-R-0079
Customer Number: 21555

NOV 2 4 2009

3. Reporting Facility

Bridge Laboratories

[redacted]
(b)(2)High, (b)(7)f

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY

Column E Explanation

I. MONKEYS

Species: Monkey
Study: 1715-09374
Animal Number: 18000, 18001
Justification:
This study was conducted in compliance with US Food and Drug Administration (FDA) Good Laboratory Practice (GLP) Regulations for Non-clinical Laboratory Studies (21CFR Part 58). Non-human primates (NHP) are selected because it is a standard non-rodent species for use in toxicology studies and a test system previously used on testing of this compound, and also because of its acceptance as possible predictor of toxic changes in man. Due to the design and scope of the study, suitable alternatives could not be identified.

Summary:
The purpose of this study is to determine the potential toxicity and toxicokinetics of a test article when administered intravenously (3-hour infusion) for 28 days to male and female Cynomolgus monkeys followed by a 28-day recovery period. The following statement was included in this protocol: "In the event of severe toxicity in which decisions are to be made regarding treatment or euthanasia of a study animal, the [Bridge] Veterinarian and Study Director will preserve the right for subsequent action." The inclusion of this statement allows intervention aimed to alleviate pain or distress.

The animals demonstrated clinical observations and were provided nutritional support by the Veterinarian. However, on SD 15 and SD 16 the animals were found dead.

II. CANINES

Species: Canine
Study: 1773-08553
Animal Number: 17202
Justification:
This study was conducted in compliance with US Food and Drug Administration (FDA) Good Laboratory Practice (GLP) Regulations for Non-clinical Laboratory Studies (21CFR Part 58). The dog is selected because it is a standard species for use in toxicology studies and because of its acceptance as a possible

predictor of toxic changes in man. Dogs are also being used as the non-rodent species per current FDA and ICH guidelines. Due to the design and scope of the study, suitable alternatives could not be identified.

Summary:
The purpose of the study is to determine the potential toxicity and toxicokinetics beagle dogs, when administered by oral gavage for at least 60 days. The following statement was included in this protocol: "In the event of severe toxicity in which decisions are to be made regarding treatment or euthanasia of a study animal, the [Bridge] Veterinarian and Study Director will preserve the right for subsequent action." The inclusion of this statement allows intervention aimed to alleviate pain or distress.

The animal demonstrated clinical observations and was evaluated by the Veterinarian. The animal was subsequently found dead.

III. RABBITS

Species: Rabbit
Study: 1765-08138
Animal Number: 1325, 1326, 1327, 1328, 1334, 1345, 1346
Justification:
The rabbit was selected because it is one of the standard species for use in reproductive toxicology studies. Rabbits are also being used as the non-rodent species per current FDA and ICH guidelines. Because this study in conducted in accordance with these regulatory guidelines, alternatives could not be considered.

Summary:
The purpose of this study is designed to provide data on the potential maternal and/or developmental toxicity and toxicokinetic profile of test article in the pregnant rabbit when administered subcutaneously during the embryo-fetal development period. The following statement was included in this protocol: "In the event of severe toxicity in which decisions are to be made regarding treatment or euthanasia of a study animal, the [Bridge] Veterinarian and Study Director will preserve the right for subsequent action." The inclusion of this statement allows intervention aimed to alleviate pain or distress.

Daily administration of the test article resulted in test article-related clinical, cageside, and/or postdose observations, which prompted evaluation by the veterinarian. These observations persisted even after the dose level was lowered. Due to study design therapeutic interventions could not be administered at that time. The animals were found dead.

Species: Rabbit
Study: 1755-07854
Animal Number: 1081, 1082, 1083, 1084,1085 and 1061
Justification:
The rabbit was selected because it is one of the standard species for use in reproductive toxicology studies. Rabbits are also being used as the non-rodent species per current FDA and ICH guidelines. Because this study in conducted in accordance with these regulatory guidelines, alternatives could not be considered. The following statement was included in this protocol: "In the event of severe toxicity in which decisions are to be made regarding treatment or euthanasia of a study animal, the [Bridge] Veterinarian and Study Director will preserve the right for subsequent action." The inclusion of this statement allows intervention aimed to alleviate pain or distress.

Summary:
The purpose of this study was to provide preliminary data on the potential maternal and/or developmental toxicity and toxicokinetic profile in the pregnant rabbit when administered orally via gavage to the pregnant rabbits during the embryo-fetal development period. Results of this study will be used to establish doses for the definitive embryo-fetal development toxicity study.

Some animals were noted to have clinical observations and the above animals were found dead.